

**PCV8****ESTIMATING POPULATION BLOOD PRESSURE CONTROL AMONG US HYPERTENSIVE PATIENTS**Yuan Y<sup>1</sup>, Chen R<sup>1</sup>, L'Italien G<sup>1</sup>, Karaniewsky R<sup>2</sup><sup>1</sup>Bristol-Myers Squibb, Princeton, NJ, USA; <sup>2</sup>Bristol-Myers Squibb, Plainsboro, NJ, USA

**OBJECTIVES:** Treatment-to-Goal analyses are commonly used to predict population blood pressure (BP) control rates for antihypertensive agents based on mean BP lowering. However, control rates are frequently inaccurate because variability in BP reduction and baseline BPs are not considered. This study presents a new methodology that improves on population BP control estimates. **METHODS:** Untreated hypertensive patients (n = 2483) from the Third National Health and Nutrition Examination Survey formed the test-sample. Monte Carlo simulation trials (MCST) of 500 patient-level BP reductions were generated from 3 underlying distributions: normal, lognormal, and beta. BP control, defined as SBP < 140 and DBP < 90 mmHg, was estimated by 3 methods: parametric- MCST-based means and variances were used to generate BP lowering data, assuming a normal distribution, and were subtracted from test-sample baseline BPs; point-estimate- mean BP reductions from MCST were directly subtracted from baseline BPs; bootstrapping- MCST BP reductions were bootstrapped with replacement and applied to the test-sample. Parametric and point-estimate results were compared to more comprehensive bootstrapping estimates for each simulation trial. We also investigated the relative performance of each method in the subgroup patients at three hypertension stages defined in the JNC VI guideline. **RESULTS:** We assumed a mean (+SD) BP lowering of 20(12) and 14(7) mmHg systolic and diastolic. Parametric, bootstrapping, and point-estimate methods projected BP control rates of 66.9, 67.3, and 75.5%, respectively. The Point-estimate method frequently projected inaccurate control rates while the parametric results were shown consistent with the bootstrap method under a wide range of model conditions. **CONCLUSIONS:** Regardless of the underlying data distribution, parametric method provides more accurate control rates than point-estimate. Since patient-level BP reduction trial data are frequently unavailable to researchers, this parametric method can be used to generate more accurate treatment to goal analyses. This methodology can be extended to other therapeutic areas to estimate treatment effectiveness.

**PCV9****META-ANALYSIS OF STATINS IN THE LOWERING OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL TO EUROPEAN ATHEROSCLEROSIS SOCIETY TARGET USING ROSUVASTATIN AS A COMMON COMPARATOR**Morrell J<sup>1</sup>, Edwards S<sup>2</sup><sup>1</sup>Fitznells Manor Surgery, Ewell, Surrey, United Kingdom;<sup>2</sup>AstraZeneca UK Ltd, Luton, Bedfordshire, United Kingdom

**OBJECTIVE:** To combine the results of the four published clinical trials comparing rosuvastatin with either atorvastatin, pravastatin or simvastatin by meta-analysis to quantify the magnitude of difference in the percentage of patients failing to achieve the European Atherosclerosis Society (EAS) target for LDL-C of <3 mmol/L at 12 weeks. Patients included in the clinical trials had an initial LDL-C  $\geq 160$  (4.1 mmol/L) and <250 mg/dL (6.5 mmol/L). **METHODS:** Meta-analysis of patients failing to achieve the EAS target at 12 weeks calculated by intention-to-treat (ITT) analysis. ITT was defined as, "patients being analysed in the treatment arm that they entered at randomisation, regardless of whether they dropped-out, received the incorrect treatment or withdrew before completion of the trial". **RESULTS:** Rosuvastatin 10mg is more effective at lowering LDL-C to the EAS target than atorvastatin 10mg, pravastatin 20mg and simvastatin 20mg at 12 weeks. There is an increase in the relative risk of failing to achieve the EAS target for LDL-C with atorvastatin 10mg (RR 2.31; 95%CI: 1.76 to 3.04), pravastatin 20mg (RR 3.91; 95%CI: 3.05 to 5.03) and simvastatin 20mg (RR 2.41; 95%CI: 1.83 to 3.16), compared to rosuvastatin 10mg. A chi-squared test was carried out to investigate possible heterogeneity in each of the comparisons. Significant heterogeneity was not detected in any of the comparisons made. **CONCLUSIONS:** Compared to rosuvastatin 10mg, there is a significant increase in the risk of failing to achieve the EAS target for LDL-C with atorvastatin 10mg, pravastatin 20mg and simvastatin 20mg at 12 weeks.

**PCV10****DEFINING OUTCOMES IN STUDIES OF BLEEDING MORBIDITY ASSOCIATED WITH ANTICOAGULATION THERAPY**Ofori BD<sup>1</sup>, Davey PG<sup>1</sup>, Goudie B<sup>2</sup>, Timoney A<sup>3</sup><sup>1</sup>University of Dundee, Dundee, United Kingdom; <sup>2</sup>Westgate Health Centre, Dundee, United Kingdom; <sup>3</sup>Tayside Health Board, Dundee, United Kingdom

**OBJECTIVES:** The reported incidence of bleeding associated with oral anticoagulation therapy varies widely. The study objectives were to identify good quality evidence about risk of bleeding and to investigate the impact of study heterogeneity on outcomes. **METHODS:** A search was made of MEDLINE and EMBASE for randomised controlled trials and inception cohort studies between January 1990 and March 2002. Selection criteria were: anticoagulation monitored by INR, percentage time within range stated, and criteria for defining a major bleed stated. The sensitivity of diagnostic criteria for bleeding events was investigated by assembling a six-month cross sectional retrospective cohort of anticoagulated patients. Outcome events in this cohort were then assessed against the criteria for "major bleeds" proposed by each reviewed study. **RESULTS:** Twelve studies were identified that met the selection criteria. Significant variation was seen in the major bleed rates across the studies